October 6, 2005

Centers for Medicare and Medicaid Services
Dr. Mark McClellan, Administrator
Office of the Administrator
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Secretary McClellan,

As I view the rollout of Medicare's Prescription Drug Benefit (Part D), which began October 1st, the complexities of the program are increasingly making it unwieldy. Many of my constituents are concerned that this costly program may not end up serving the purpose of easing the financial burden of prescription drugs for Medicare recipients. My offices in Hartford, Connecticut, and Washington, D.C. have been approached by Centers for Medicare and Medicaid (CMS) staff who are working to launch the benefit, and we appreciate their diligence. Nevertheless, on behalf of seniors and other Medicare beneficiaries, I am compelled to request responses to the following open questions:

- I have just learned that there are important errors contained in the CMS Part B handbook that will be sent out to all seniors today. These errors influence whether seniors who have prescription drug coverage from their former employees choose to take part in the Part D program, or what prescriptions drug plans (PDP) seniors who are eligible for the part D low income subsidy choose. How did these errors occur? What is the process by which CMS edits its materials? I was disturbed to learn that CMS does not yet know who was responsible for these errors and at what point in the process they occurred. I am concerned that without proper methods to record processes and to hold people accountable for their work, systemic errors can occur again in the implementation process. What steps is CMS taking to get corrected information to seniors?

- The program is confusing to many, including our most vulnerable citizens who may be cognitively impaired, suffer from mental illness or developmental disabilities, have limited mobility, and have little to no access to computer technology. Surveys indicate that many seniors may simply decline to participate in the benefit even though it could result in cost savings to them. Or, low-income seniors will be randomly assigned and enrolled in a PDP that may not be the best for them. How is CMS assuring that our most vulnerable seniors are served and

are empowered to make an informed decision? How are low-income and seniors with disabilities being contacted given the difficulties in reaching these vulnerable populations? Once they have been contacted, how will decisions be made regarding the ideal benefit plan if the patient is unable to decide for him or herself?

- Different drug plans will offer different formularies, thereby requiring changes in medications for some patients to receive a benefit. This will necessitate the involvement of the patient's physician to either experiment in finding an effective replacement drug, or participate in the appeals process with CMS in order to continue with an existing successful regimen. What steps has CMS taken to mobilize physicians in this effort? Is there a plan to compensate providers for the extra time, effort and laboratory tests required to coordinate a switch in regimen?

- There are reports that the companies are aggressively marketing their PDP's to seniors, sometimes in ways that are unfair, coercive, and even illegal. How is CMS overseeing the marketing of Part D drug plans? What safeguards are in place to assure that seniors are getting the right information, in the right place at the right time? In what way will violations of the marketing rules be dealt?

- As written, Part D excludes coverage for anti-seizure and anti-anxiety drugs such as Phenobarbital and Benzodiazepines that are widely used amongst the elderly. These medicines are not easily replaced. What exceptions will or can be made to the rule? Is it true the alternative medicines are much more expensive? And if so, does this make good policy sense?

- CMS has yet to clarify how Medicaid coverage will coordinate with Part D. Over the counter (OTC) medications are covered by Medicaid. When Medicaid recipients are obliged to transfer their coverage to Medicare, we have been told that states may elect to cover the costs of these frequently essential medicines. What happens if the state does not elect to cover OTC products? Anemics need iron, arthritics require Tylenol, and osteoporotics must have calcium. How will this gap be filled?

- Many Medicaid recipients are infirm and in the end will have a PDP automatically and randomly assigned to them. Their old Medicaid benefits will stop December 31, 2005 and their new Medicare Part D benefit will begin January 1st, 2006. I imagine this will require an overwhelming amount of data management and transfer. I feel that it is very possible because of the sheer volume of people and data that there will be a failure in the automatic enrollment process and some patients will be left without medicines. What safeguards exist to make sure that this does not happen? If there is a failure, what are there contingency plans to make sure that seniors get the medicines they need?

- Long term care pharmacies are often more expensive than their discounted counterparts because they provide added, much-needed services to the long-term

care community. How, in a competitive bid situation, can CMS guarantee the survival of these essential players in patient safety and care? And in the greater context, what are the mechanisms in place to assure that quality is not displaced by ever more competitive discounting? Lower priced pharmaceuticals will do nothing to assure quality medical care.

As suggested by the concerns I have expressed above, success or failure resides in the details of this exceedingly complex change-over of entitlement benefits. We must all work diligently to *anticipate* what challenges may arise and who will be made to suffer if we fail. The federal benefits provided involve the safety, well-being, health, and even the lives of our citizens. The cost of the new Medicare pharmacy benefit is already exceedingly high. I ask that you take all possible steps including the clarifications and decisions I have listed above to be sure that it does not cost us more than money.

Best personal regards,

Sincerely,

Joseph I. Lieberman
UNITED STATES SENATOR